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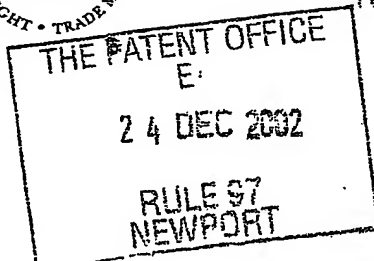
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08534141001

Patents ADP number (if you know it)

If the applicant is a corporate body, give the country/state of its incorporation

4. Title of the invention

A PUPILOMETER

5. Name of your agent (if you have one)

"Address for service" in the United Kingdom to which all correspondence should be sent (including the postcode)

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Description

12

Claim(s)

6

Abstract

1

Drawing(s)

10

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Statement of inventorship and right to grant of a patent (Patents Form 7/77)

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A Pupilometer

Field of the Invention

This invention relates to an apparatus commonly known as a pupilometer.

Background of the Invention

In the neurological assessment of an unconscious patient, pupil response is known to be a vital aspect of the diagnostic process. Regular assessment of the size, reactivity to light and equality of pupils is essential for early recognition of neurological deterioration in situations where intra-cranial pathology is a threat. As such this assessment is regularly carried out in paramedic, intensive and high dependency care situations.

The current method of practice is to manually measure these aspects using a bright light, which stimulates reactivity of the pupil, and make a note of the dilation compared to the original size of the pupil. Actual measurements taken are then compared with a card having different pupil sizes marked thereon. This method of assessment is time consuming, and subjective.

Pupilometers have been developed for use in the assessment of eye shape and condition, monitoring tiredness, and in the detection of drugs or alcohol in a person.

A hand-held pupilometer is described in US 6,022,109 (Dal Sante). This pupilometer detects and measures pupil diameter and pupil response to a light stimulus. Also described is software to permit the diagnosis of alcohol or drug presence. However, use of this pupilometer requires the active participation of the user.

Another hand-held pupilometer is described in US 6,199,985 (Anderson). This patent describes a method for measuring optical power output from the pupil. However, the pupilometer described in the patent requires complex optometric components.

Another hand-held pupilometer is described in US 6,260,968 (Stark). The device described includes an LCD display via which prompts to the operator are given. The pupilometer described in this patent uses a "flying spot" algorithm to establish a circumference fitting the pupil, and the pupil radius. The pupilometer includes software to aid diagnosis. Again, the pupilometer described in this patent requires complex optometric components.

It would therefore be desirable to provide an improved pupilometer.

Summary of the Invention

According to one aspect of the invention there is provided a pupilometer as specified in Claim 1.

According to another aspect of the invention, there is provided image processing software as specified in Claim 29.

The software may be embodied on a record medium, stored in a computer memory, embodied in read only memory, or carried on an electrical signal.

According to another aspect of the invention, there is provided a process for obtaining pupil image information as specified in Claim 30.

Brief Description of the Drawings

In the drawings, which illustrate exemplary embodiments of pupilometers according to the invention:

Figure 1 is a schematic representation of a perfect eye;

Figure 2 is a block diagram of a pupilometer;

Figure 3 is a schematic representation of an eyeball;

Figure 4 is an image of an eye under ambient light;

Figure 5 is an image of an eye under infra-red light;

Figure 6 shows a raw image taken by the pupilometer before any image processing has taken place;

Figure 7 shows the image of Figure 6 after the identification of dark pixels;

Figure 8 is a table used to identify an edge;

Figure 9 shows the image of Figure 7 after identification of the pupil edge;

Figure 10 shows the image of Figure 9 at the beginning of a spiral search;

Figure 11 shows the image of Figure 9 with adjoining pupil edge pixels connected to one another;

Figure 12 is a table illustrating a recursive flood-fill algorithm;

Figure 13 shows the image of Figure 11 with the rectangular dimension of the pupil identified;

Figure 14 shows an image of a part of an eye close to the pupil when subjected to highlights from infra-red LED's of the pupilometer;

Figure 15 shows the image of Figure 14 with the highlights marked;

Figure 16 is a schematic representation of the marked highlights of Figure 15;

Figure 17 shows the image of Figure 14 with the distance from the highlight to the centre marked;

Figure 18 shows the image of Figure 14 with the distance between the two highlights marked;

Figure 19 is a graph showing the reaction over time of a pupil diameter to a light stimulation;

Figure 20 is a schematic cross-section of a hand-held pupilometer;

Figure 21 is a plan view of the pupilometer illustrated in Figure 20; and

Figure 22 is a block diagram of the pupilometer shown in Figures 20 and 21.

Detailed Description of the Preferred Embodiments

Figure 2 illustrates the components of an embodiment of the pupilometer. The pupilometer comprises a camera board 10 including a camera, which in the example is a CMOS (Complementary Metal Oxide Semiconductor) camera 11, a filter 12, which in the example is an infra-red pass filter, a pair of infra-red light emitting diodes (IR LED's) 13, and a light emitting diode (LED) 14 for emitting white light. The camera 11 and LED's 13, 14 are mounted on a board, which in the example is a printed circuit board 15, the filter 12 being mounted in front of the lens of the camera 11.

The camera board 10 is connected by suitable cabling to a control board 20, which mounts an analogue interface 21, a micro-controller 22, a memory 23 and a Universal Serial Bus (USB) interface 24. The analogue interface 21, memory 23 and USB interface 24 are each connected to the micro-controller 22 by suitable cabling 25. The analogue

interface 21 receives an analogue video signal from the camera board 10 and converts said signal into a digital form. The micro-controller 22 provides control signals for image acquisition from the camera board 10, and transmission of image data to a computer programmed with custom pupil detection and measurement software, which in the example is a laptop computer 26 connected to the micro-controller 22 via a USB interface 24. However, the computer programmed with custom pupil detection and measurement software could easily form part of a hand held pupilometer device. Such a device is described with reference to Figures 20 to 22.

The control board 20 also mounts a memory module 23 which provides additional static RAM for storage of image data acquired from the camera board 10 prior to transmission of the image data to the computer 26, with the USB interface 24 providing a physical interface for the conversion and transmission of image frames to the computer 26 over a standard USB interface.

The computer 26 of the example runs the operating system, "Microsoft Windows 95", and custom software which detects and measures the pupil in the images generated by the camera.

Referring now to Figure 3, the IR LED's 13 shine light towards the eyeball 30, but to the sides of the pupil 31. By virtue of illuminating the eyeball by shining light to the sides of the pupil 31, most of the rays of light entering the pupil are internally reflected and absorbed by the retina, and thus the camera only sees light reflected from the surface of the eye, with the pupil appearing as a dark area.

The purpose of the infra-red pass filter 12 is to stop all visible light entering the camera 11, which eliminates the effects of ambient light conditions, thereby permitting accurate control of the instrument.

Figures 4 and 5 illustrate the difference in appearance of an eye under ambient light conditions (see Figure 4) and infra red lights (see Figure 5). In Figure 5, the contrast between the pupil 3 and the iris 2 is increased compared to Figure 4. Also, there is much less surrounding detail in Figure 5 compared to Figure 4.

The reflections from the IR LED's 13 can be seen clearly in Figure 5, and the distance between these specular highlights is used as measure of the distance from the camera to the eye (the closer the IR LED's are to the eye, the further apart are the highlights).

Referring now to Figures 20 to 22, there is shown a hand-held pupillometer, which comprises a camera board 110 including a camera, which in the example is a CMOS (Complementary Metal Oxide Semiconductor) camera 111, a filter 112, which in the example is an infra-red pass filter, a pair of infra-red light emitting diodes (IR LED's) 113, and a light emitting diode (LED) 114 for emitting white light. The camera 111 and LED's 113, 114 are mounted on a board, which in the example is a printed circuit board 115, the filter 112 being mounted in front of the lens of the camera 111.

The camera board 110 is connected to a control board 120, which mounts an analogue interface 121, a micro-controller 122, a memory 123 and a computer interface 106. The analogue interface 121, memory 123 and computer interface 106 are each connected to the micro-controller 122 by suitable cabling 125. The analogue interface 121 receives an analogue video signal from the camera board 110 and converts said signal into a digital form. The micro-controller 122 provides control signals for image acquisition from the camera board 110. Further, the micro-controller 122 transmits image data to, and runs, custom pupil detection and measurement software.

As mentioned above, the control board 120 also mounts a memory module 123 which provides additional static RAM for storage of image data acquired from the camera

board 110 for use by the custom pupil detection and measurement software of the micro-controller.

The computer interface 106 provides a physical interface for transmission of data to an external computer. It may be desirable to store test results in patients' notes, or for research purposes, and whilst the hand-held device 100 has sufficient memory to record a number of results, to use the device continually, the memory 123 must be cleared from time to time.

As with the device described with reference to Figure 3, the IR LED's 113 shine light towards the eyeball 30, but to the sides of the pupil 31. By virtue of illuminating the eyeball by shining light to the sides of the pupil 31, most of the rays of light entering the pupil are internally reflected and absorbed by the retina, and thus the camera only sees light reflected from the surface of the eye, with the pupil appearing as a dark area.

Pupilometer Software

The main function of the software is to interpret the image of the eye and detect, or classify, the pupil within that image. The software was developed using Borland Delphi and in the example executes under the Microsoft Windows operating system.

The basic requirement is the ability to detect a circle (i.e the pupil) within the image and known algorithms available for the performance of this task include the Hough transform, parametric matching and neural network classification. However, these methods are computationally intensive and require a floating-point numeric processor in order to achieve optimal performance.

One aim of the invention is to provide a standalone hand-held pupilometer. This means that a relatively low specification microprocessor must be used and therefore the

algorithm of the invention is a simple multi-stage classification algorithm, which uses integer mathematical functions to classify the pupil within the image.

Referring now to Figure 1, there is shown a model of a perfect eye, i.e. the iris 2 is at the centre of the eyeball 1, with the pupil 3 being at the centre of the iris 2. Further, both the pupil 3 and the iris 2 are perfect circles, the boundary 4 between the iris 2 and the pupil 3 is sharp, and the darkest region of the eye is the pupil 3.

The software of the invention makes certain assumptions based on the model of the perfect eye described above, those assumptions being:

- 1) The pupil will be the darkest area of the image;
- 2) The pupil – iris boundary will have the sharpest edge;
- 3) The pupil – iris boundary will be elliptical.

The software provides three principal functions;

1. *Pupil classification*: the detection and measurement of the pupil within the image of the eye.
2. *Ranging*: the detection and measurement of the IR LED reflections on the eye surface allowing calculation of distance from camera to eye.
3. *Stimulation*: measurement of the pupil reflex action to light stimulation.

Pupil Classification

The classification algorithm of the invention provides for the differentiation of the pupil from other dark areas of the image, such as shadows, and from interference within the pupil boundary, for example eyelashes and highlights.

To acquire an image from the control board 20, the software sends a request via the USB interface 24 and waits for the image to be returned. The image is returned as a two-dimensional (128 x 128 pixel) array of 6 bit values, with each value representing the greyscale intensity of the relevant image pixel in the range 0 to 63. This image is then subjected to the following processing steps:

- 1) As the image array is read into a Delphi program, the value of the darkest pixel (V_d) is identified and stored. A dark threshold level (T_d) is calculated as $T_d = V_d + 4$ based on this darkest value, the constant 4 ensuring that the dark pixel range is 6% lighter than the darkest pixel V_d – see Figure 6.
- 2) All image pixels with values of less than or equal to this dark threshold (T_d) are assigned to the *PUPIL* class – see Figure 7.
- 3) The edge values across each of these *PUPIL* class pixels are calculated using the simple gradient algorithm $|P_4 - P_0| + |P_4 - P_1| + |P_4 - P_2| + |P_4 - P_5| + |P_4 - P_8| + |P_4 - P_7| + |P_4 - P_6| + |P_4 - P_3| = G$ the gross radial gradient. This algorithm produces the gross radial gradient (G) across the central pixel (P_4) – see Figure 8.
- 4) All image pixels with edge values (G) of greater than or equal to 8 are assigned to the *PUPIL EDGE* class - see Figure 9. The pupil edge value of 8 was selected using empirical methods as a value discriminating valid edge pixels.
- 5) A spiral search from the centre of the image, is used to locate the first *PUPIL EDGE* pixel and this is assumed to lie on the pupil boundary – see Figure 10.

- 6) All adjoining *PUPIL EDGE* pixels are connected using a recursive flood fill algorithm. The algorithm also tracks the extents of the adjoining pixels, from which the width and height of pupil region are derived – see Figure 11.

Recursive flood fill

The fill algorithm sets the target pixel and tests each of its four neighbours, in north-west-south-east order, for another *PUPIL EDGE* pixel. As soon as such a pixel is found, the algorithm re-calls itself with this new pixel as its target. An enlarged view of a typical fill pattern is shown in Figure 10. The first branch is filled by the routine calling itself nine times and stops when no further *PUPIL EDGE* pixels are found, the second branch (dotted arrows) search then starts. In this way, the routine continues until all adjoining *PUPIL EDGE* pixels have been set – see Figure 12.

- 7) The rectangular dimension of the pupil region is calculated from the extents of the flood fill and an ellipse consisting of thirty-two points is fitted inside this rectangle. If twelve or more of these points hit a *PUPIL EDGE* pixel the region is classified as the *PUPIL* and the range detection phase begins; if not the search re-starts with a new video image. The pupil diameter is defined as the maximum diameter of the ellipse – see Figure 13.

Ranging

When a valid pupil has been classified it is known that the highlights from the infra red LEDs will appear in the image within close proximity to the pupil. Therefore to improve speed of calculation and removal of artifacts from eyelids etc, only the area around the pupil is searched.

With reference to Figure 14, an area twelve pixels above and below the pupil is scanned to find the ***BRIGHTEST*** pixel level.

With reference to Figure 15, the area is rescanned and pixels with a value greater than ***BRIGHTEST-8*** are marked as ***HIGHLIGHT*** pixels. The maximum x/y extent of these ***HIGHLIGHT*** pixels is recorded and the centre of the extents is calculated.

$$\text{Centre X} = (\text{Max Highlight X} - \text{Min Highlight X}) / 2$$

$$\text{Centre Y} = (\text{Max Highlight Y} - \text{Min Highlight Y}) / 2$$

Figure 16 illustrates horizontal lines of pixels, starting from the centre pixel (PASS 1) and expanding one pixel vertically above and below the centre line (PASS 2...), which are scanned to the right hand extents until a ***HIGHLIGHT*** pixel is found.

Figure 17 shows the ***HIGHLIGHT*** area flood-filled, with the centre of the area calculated from the extents of the flood-fill. Steps 16 and 17 are then repeated for the pixels on the left-hand side of the centre pixel.

Figure 18 illustrates the next step, where with both highlight areas identified, the horizontal distance between their centres is used as a measure of the range.

Stimulation

A lookup table is used to calculate the absolute pupil diameter in millimetres from the measures of pupil diameter and range. When a valid pupil measurement has been made, the system can start a stimulation cycle to obtain the pupil constriction response curve after stimulus by a bright white light source.

During the stimulation cycle, the pupil diameter is continuously recorded whilst the white LED is energised for a brief period. A graph, illustrated in Figure 19, of the pupil diameter is then drawn, a typical response curve is shown below.

Where the following measurements can be taken;

L	Latency (ms)	Time between start of stimulus and beginning of contraction
A	Contraction amplitude (mm)	Difference between the mean post-stimulus diameter and minimum per-stimulus diameter
Tc	Contraction time (ms)	Time from end of latency to minimum pupil diameter

The response curve can be used in itself in diagnosis, or the response curve can form part of an expert system, which may generate a diagnosis.

The invention provides a simple and relatively low cost device for use in a variety of operational situations. Further, it provides a reliable and objective means of assessing pupil response.

Claims

1. A pupilometer comprising image capturing means, illumination means, stimulation means, and image processing software, wherein said illumination means generates and emits light of a first wave-length, and said stimulation means generates and emits light of a second wavelength, and wherein said illumination means is arranged to one or both sides of said image capturing means and, in use, shines light towards the eyeball at an angle to the axis of the pupil.
2. A pupilometer according to Claim 1, wherein the wavelength of the light generated by said illumination means is in the infra-red spectrum.
3. A pupilometer according to Claim 2, wherein said illumination means comprises an infra-red light emitting diode.
4. A pupilometer according to any preceding claim, wherein said illumination means comprises a light emitting diode generating and emitting light in the visible spectrum.
5. A pupilometer according to any preceding claim, wherein said image capturing means comprises a camera.
6. A pupilometer according to Claim 5, further comprising a filter mounted on the camera lens.
7. A pupilometer according to Claim 5 or 6, wherein said camera generates a video signal.

8. A pupilometer according to any of Claims 5 to 7, wherein said camera is a complementary metal oxide semiconductor device.
9. A pupilometer according to any preceding claim, wherein said image detection means further includes a micro-controller including a micro-processor.
10. A pupilometer according to any preceding claim, further comprising an analogue to digital converter arranged between said camera and said micro-controller.
11. A pupilometer according to any preceding claim, further comprising memory means.
12. A pupilometer according to any preceding claim, further comprising data input means and display means.
13. A pupilometer according to any preceding claim, further comprising an interface for linking said pupilometer to an external computer.
14. A pupilometer according to any preceding claim, wherein said pupilometer is a hand-held device, wherein said hand held device mounts a power supply, said image capturing means, illumination means, stimulation means, an image processing software, data input means, display means, and a computer interface, and wherein said hand-held device includes a hand grip.
15. A pupilometer according to Claim 14, wherein said power supply consists of a rechargeable battery.
16. A pupilometer according to any preceding claim, wherein said image processing software includes an algorithm, wherein said algorithm:
 - i) commands the illuminating means to illuminate an eye;

- ii) detects the pupil within the image of the eye;
 - iii) measures the size of the detected pupil;
 - iv) establishes the distance of the from the camera to the eye;
 - v) stimulates a pupil reflex action; and
 - vi) measures the pupil reflex action.
17. A pupilometer according to Claim 16, wherein the step of detecting the pupil within the image of the eye consists of acquiring image data in the form of a two-dimensional array of values, each value representing the greyscale intensity of an image pixel, and processing said image data according to the following sub-steps:
- i) Read the image data into a program;
 - ii) Run the program to identify the darkest pixel;
 - iii) Calculate a threshold value as a function of the darkness of the darkest pixel;
 - iv) Identify and store all pixels as dark or darker than the threshold value as of the pupil class;
 - v) Calculate the edge value across each pixel in the pupil class;
 - vi) Establish an edge value threshold value, wherein all image pixels with an edge value greater than or equal to the threshold are identified and stored as pupil edge class;
 - vii) Execute a search of the image to locate the first pixel in the pupil edge class and assume that this pixel lies on the pupil boundary;

- viii) Run an algorithm to connect adjoining pupil edge pixels;
 - ix) Calculate the rectangular dimension of the pupil region, and fit an ellipse consisting of n points inside the rectangle;
 - x) If more than n/c (where c is a nominal value) of said n points coincide with a pupil edge pixel classify the region as the pupil and if less than n/c re-start the search with a new image; and
 - xi) Record pupil radius as the maximum radius of the ellipse.
18. A pupilometer according to Claim 17, wherein said program is a Delphi program.
 19. A pupilometer according to Claim 17 or 18, wherein the said edge value is calculated according to a gradient algorithm, wherein the gradient algorithm provides that the gross radial gradient (G) across a central pixel P_4 in an eight pixel array equals $|P_4-P_0| + |P_4-P_1| + |P_4-P_2| + |P_4-P_5| + |P_4-P_8| + |P_4-P_7| + |P_4-P_6| + |P_4-P_3| = G$, and wherein the edge value threshold is a function of G the gross radial gradient.
 20. A pupilometer according to any of Claims 17 to 19, wherein said search of the image to locate the first pixel in the pupil edge class is a spiral search from the centre of the image.
 21. A pupilometer according to any of Claims 17 to 20, wherein said algorithm is a recursive flood fill algorithm.
 22. A pupilometer according to any of Claims 17 to 21, wherein n equals 32.
 23. A pupilometer according to any of Claims 17 to 22, wherein c equals 2.

24. A pupilometer according to any of Claims 17 to 23, wherein the step of establishing the distance of the pupilometer from the eye includes identifying highlights resulting from the illumination means by the following steps:
- i) scan the image for the brightest pixel;
 - ii) re-scan the image and mark those pixels with a value greater than the brightest eight as highlight pixels;
 - iii) Record the extents of the highlight pixels in the x and y directions;
 - iv) Calculate the centre of the extents;
 - v) Perform a search of the highlight extents until a highlight pixel is found;
 - vi) Flood-fill the area around the highlight pixel and calculate the centre of the fill area.
 - vii) Repeat steps v and vi for the other side of the highlight extents
 - viii) Calculate the horizontal distance between the centres of the highlight areas and store said value as a range value.
25. A pupilometer according to Claim 24, wherein the said search of the highlight extents consists the following step:
- i) Perform from the centre of the extents a multi-pass expanding search of one side of the highlight extents until a highlight pixel is found;
26. A pupilometer according to Claim 25, wherein stimulation of a pupil reflex reaction comprises the following steps:

- i) establish absolute pupil diameter using the measures of pupil diameter and range;
 - ii) commence a stimulation cycle by stimulating the pupil with a bright light source for a time period;
 - iii) record a pupil constriction response curve during and after said stimulus;
 - iv) display pupil constriction response curve on said display.
27. A pupilometer according to Claim 26, wherein the absolute pupil diameter is established by reference to a look-up table.
28. A pupilometer according to Claim 26 or 27, wherein said bright light source is a bright white light source.
29. Image processing software comprising computer program instructions for causing a computer to perform the algorithm steps set out in any of Claims 16 to 27.
30. A process for obtaining pupil image information comprising the steps of:
- i) Illuminating a pupil with the illumination means of a pupilometer according to any of Claims 1 to 29; and
 - ii) Running image processing software according to Claim 30.
31. A pupilometer substantially as shown in, and as described with reference to, the drawings.

Abstract

A Pupilometer

A pupilometer comprises image capturing means, illumination means, stimulation means, and image processing software, wherein said illumination means generates and emits light of a first wave-length, and said stimulation means generates and emits light of a second wavelength, and wherein said illumination means is arranged to one or both sides of said image capturing means and, in use, shines light towards the eyeball at an angle to the axis of the pupil.

1/10

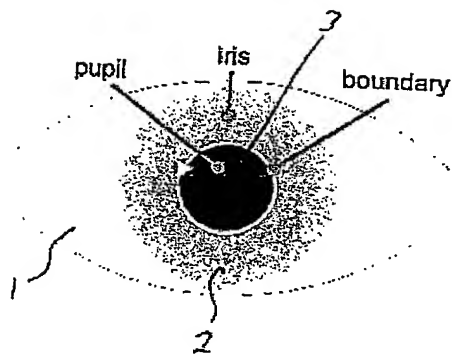


Figure 1

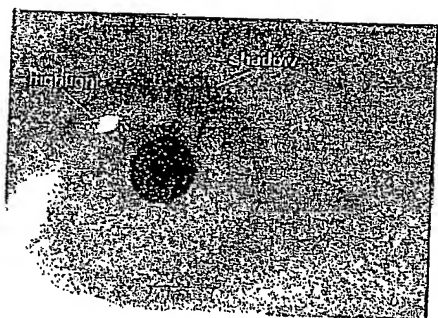


Figure 4

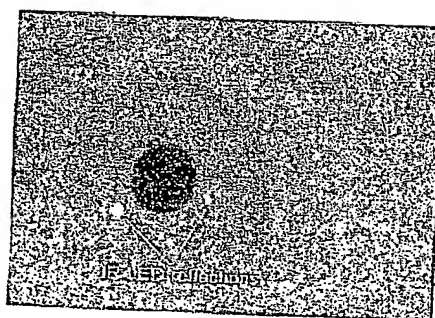


Figure 5

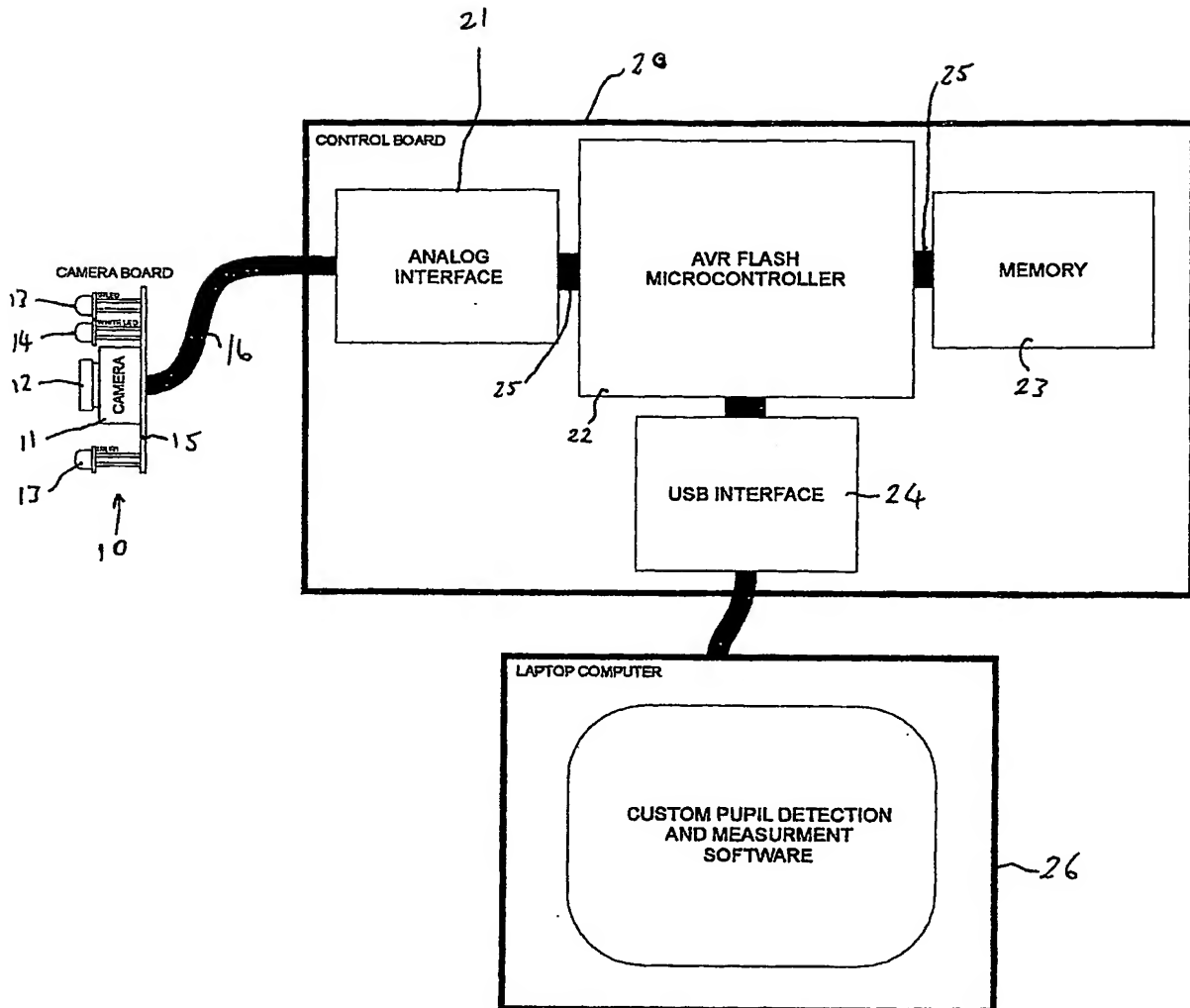


Figure 2

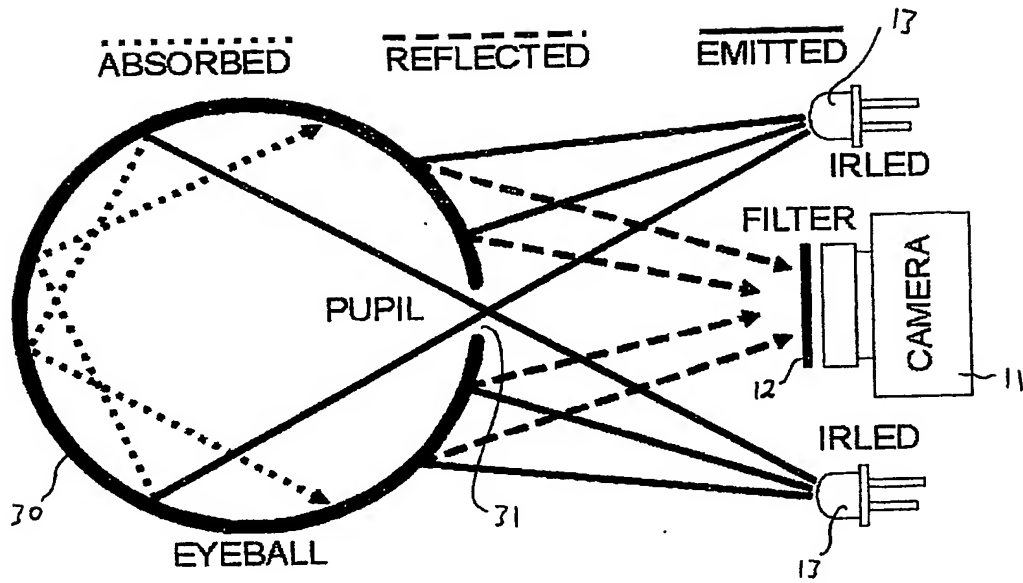


Figure 3

P_0	P_1	P_2
P_3	P_4	P_5
P_6	P_7	P_8

Where G is the magnitude of the gradient across target pixel P_4

Figure 8

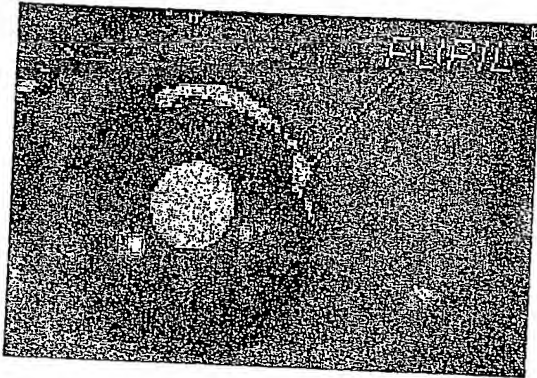


Figure 7

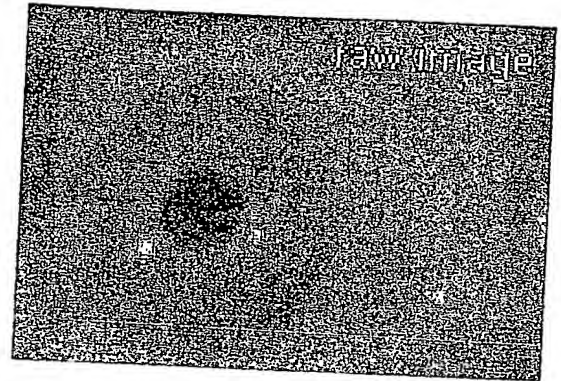


Figure 6

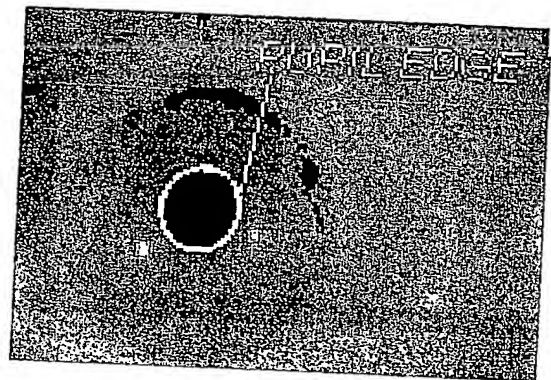


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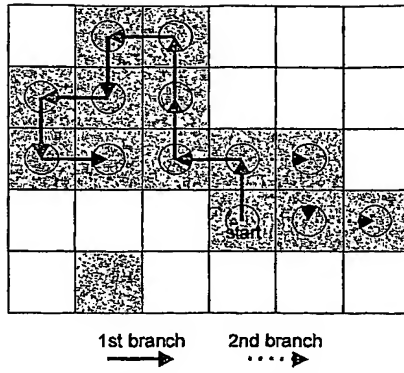


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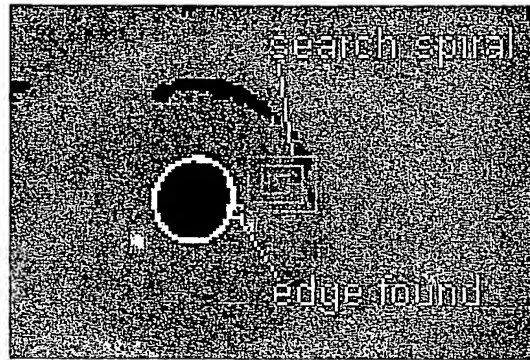
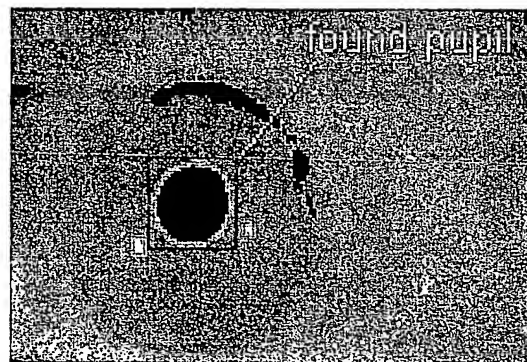
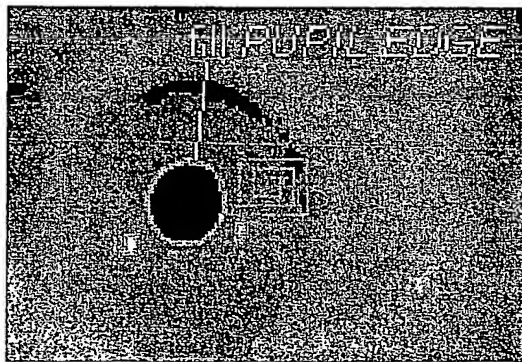


Figure 10

Figure 11

Figure 13



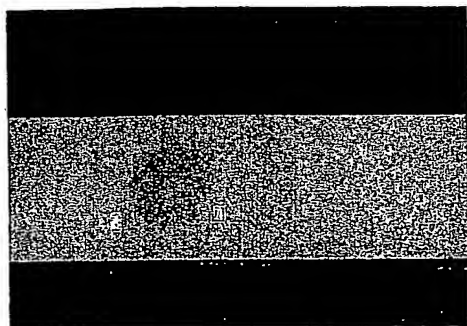


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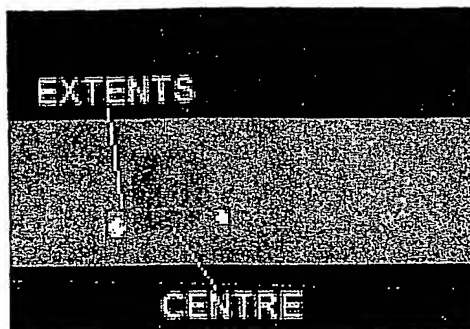


Figure 15

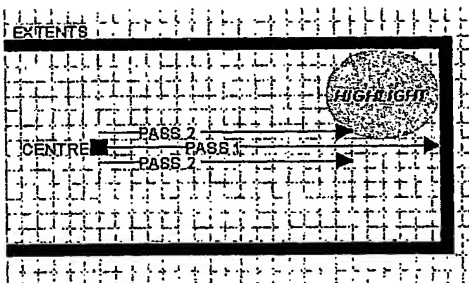


Figure 16

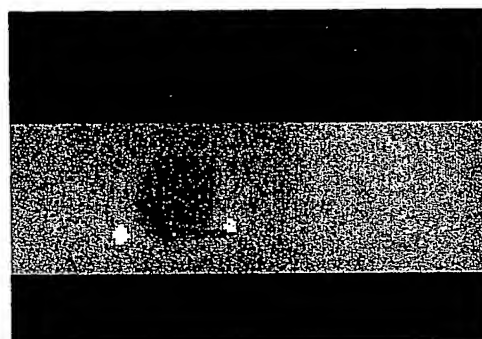


Figure 17

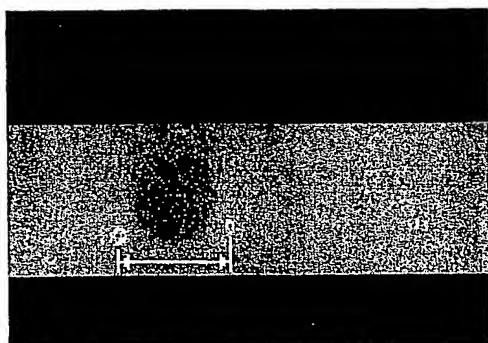


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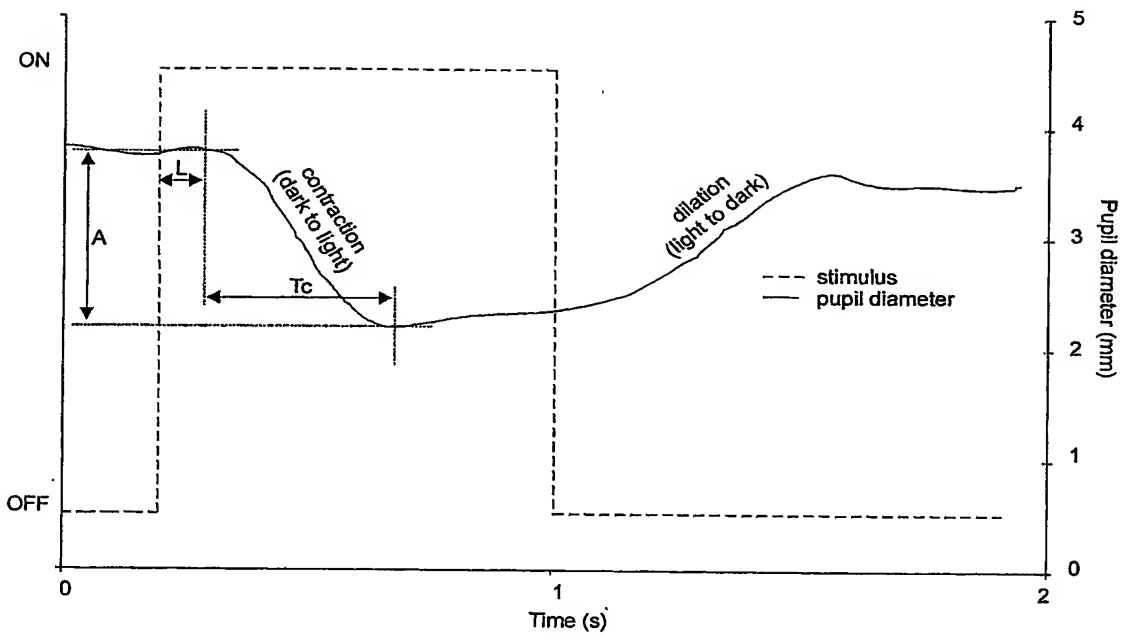


Figure 19

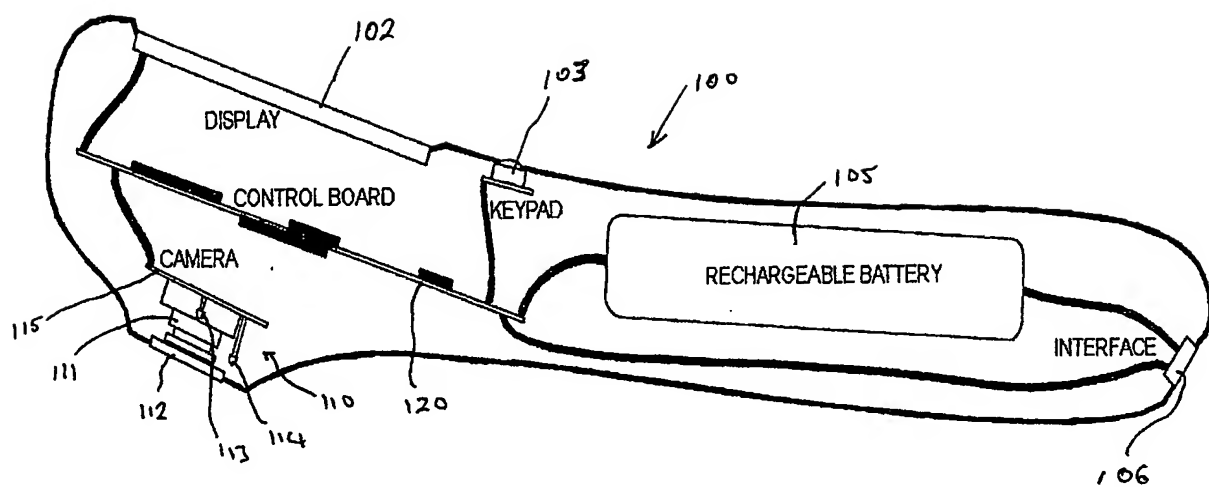


Figure 20

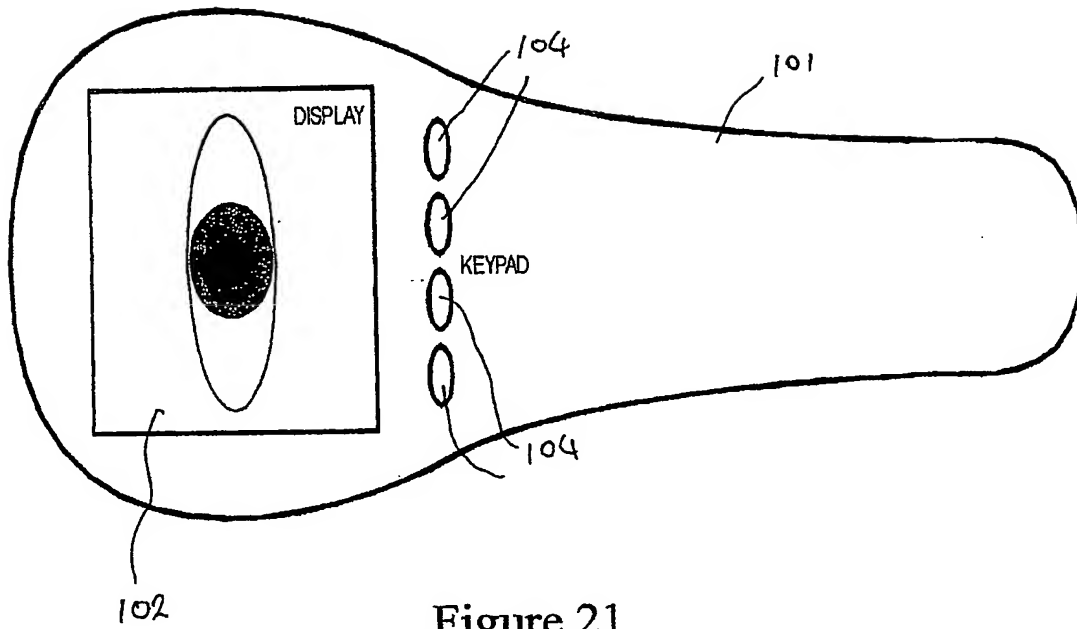
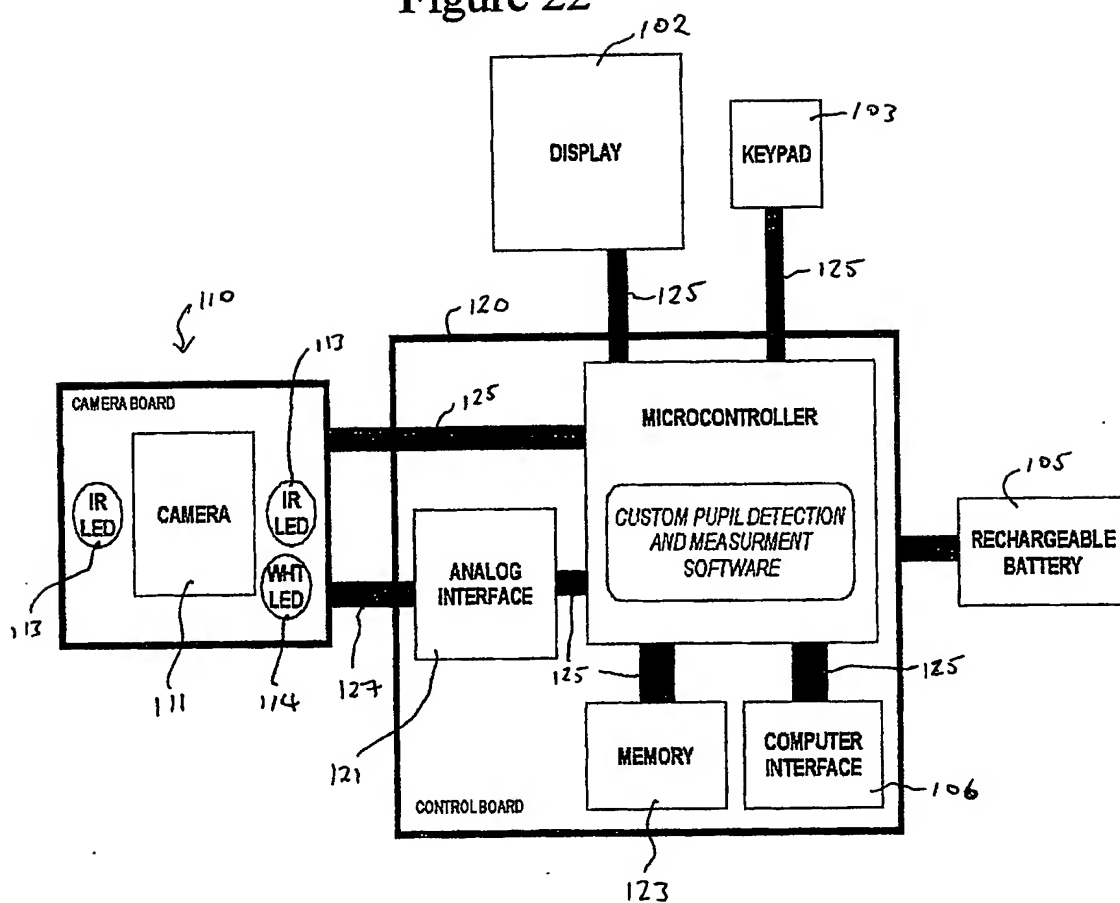


Figure 21

Figure 22



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